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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,484	07/09/2001	Daniel Cohen	GEN-T111XC3D2	6608
23557	7590	03/02/2005	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,484

Applicant(s)

COHEN ET AL

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-53 and 56-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-53, 56-59 and 61-66 is/are rejected.
- 7) ☒ Claim(s) 60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 22, 2004 has been entered.

Priority

2. The current application claims priority to a series of cases dating back to 1997. However, the claims are not given priority to applications 08/996,306 and 60/099,658 because in the current application SEQ ID NO: 179 is 56,520 nucleotides while in those parent applications, the largest sequences were 56,516 nucleotides. Consequently, there is no possibility that these applications provide full descriptive support for SEQ ID NO: 179, and priority to these applications is denied. Therefore, for purposes of prior art, the priority date of this application is limited to 09/218,207, filed December 22, 1998, which provides the full 56,520 nucleotides of SEQ ID NO: 179.

Claim Rejections - 35 USC § 112

3. The rejection of claims 54 and 55 under 35 U.S.C. 112, first paragraph, is moot in view of the cancellation of those claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 50, 59 and 61-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Weier et al (Hum. Genet. (1991) 87:489-494) as evidenced by Genbank Accession No. AC100813 (March 2003).

Weier et al teaches an isolated human chromosome 8, which was flow sorted to purify the sequence (see abstract and page 490, column 2). The current PG-1 sequences are all derived from chromosome 8 as admitted by the specification at page 28. So chromosome 8 is a sequence of more than 500 nucleotides which comprises SEQ ID NO: 179. The chromosome comprises the complement inherently.

Genbank Accession No. AC100813 has a 99.8% alignment with nucleotides 3899-4996 as shown in the alignment below and represents a sequence within chromosome 8. This sequence comprises a region from nucleotide 51963 to 51354, at least, which is 100% identical so that there is a region of over 600 contiguous basepairs on chromosome 8.

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ORIGIN

Query Match 90.7%; Score 996; DB 2; Length 165799;
Best Local Similarity 99.8%; Pred. No. 0;
Matches 1096; Conservative 0; Mismatches 2; Indels 0; Gaps 0;

Qy 1 GTTCTTGTTCCTGCATTTTATTTTATTGTATGGAGGGGACAAATAATTATTTCTGT 60 /
Db 52074 GTTCTTGTTCCTGCATTTTATTTTATTGTATGGAGGGGACAAATAATTATTTCTGT 52015

Qy 61 TTAGTAACAGAGCAGGGTATTTGAATTATTAGGGTCTTTTCTGCAGTCTGGGTTTCC 120
Db 52014 TTAGTAACAGAGCAGGGTATTTGAATTATTAGGGTCTTTTCTGCAATCTGGGTTTCC 51955

Qy 121 TGTGTACACAAAGCTACCTTTCAATATTTTATTGTTTCTGTTAAGATTAAATCAATAG 180
Db 51954 TGTGTACACAAAGCTACCTTTCAATATTTTATTGTTTCTGTTAAGATTAAATCAATAG 51895

Qy 181 AGGAATAAATAGCTATCTTCAACATAAGACCCAAAGGAAAAAGATTATAGTGATGTTT 240
Db 51894 AGGAATAAATAGCTATCTTCAACATAAGACCCAAAGGAAAAAGATTATAGTGATGTTT 51835

Qy 241 TGTACCTTATTTTACCTGTGACTTTGTACCATTAACCTTTGTCACTGAGATGTTTGA 300
Db 51834 TGTACCTTATTTTACCTGTGACTTTGTACCATTAACCTTTGTCACTGAGATGTTTGA 51775

Qy 301 TTAATAATTTAGCTTGTCTTTCTGTTTGTAGGACACTCTTTTCTTGAATTGTT 360
Db 51774 TTAATAATTTAGCTTGTCTTTCTGTTTGTAGGACACTCTTTTCTTGAATTGTT 51715

Qy 361 TTTATCAGCTTTCGTTTGCAAGGCTAGTGATGATTCTTGTCTGTATAAAGTATTGTT 420
Db 51714 TTTATCAGCTTTCGTTTGCAAGGCTAGTGATGATTCTTGTCTGTATAAAGTATTGTT 51655

Qy 421 GACTCATTTCTGAAGGGAGTTTATAGTAATTTAAGAGGTTATAAGTTTAAATAAAGGT 480
Db 51654 GACTCATTTCTGAAGGGAGTTTATAGTAATTTAAGAGGTTATAAGTTTAAATAAAGGT 51595

Qy 481 TTATTAATTTATATATATTAAGAGGCAATTTAAATAAATTTTAAATGACATTT 540
Db 51594 TTATTAATTTATATATATTAAGAGGCAATTTAAATAAATTTTAAATGACATTT 51535

Qy 541 TTACACCTTTCAACTCTAGGTTTAAAAATAAGTGGTTCACAGTAGTCTTGCAGAGAA 600
Db 51534 TTACACCTTTCAACTCTAGGTTTAAAAATAAGTGGTTCACAGTAGTCTTGCAGAGAA 51475

Qy 601 TATTTCTTTTACATAGAATTTTAAAGCTGAAGAGAAGTAGTAGGTCCATGAGATT 660
Db 51474 TATTTCTTTTACATAGAATTTTAAAGCTGAAGAGAAGTAGTAGGTCCATGAGATT 51415

Qy 661 ATGATCTGTGCTTGGCAGGTAAACCTGCTTCCAACAAATTTAGTTGGATTTTCTTGGAT 720
Db 51414 ATGATCTGTGCTTGGCAGGTAAACCTGCTTCCAACAAATTTAGTTGGATTTTCTTGGAT 51355

Qy 721 TCTGGGTAAATACCTTTTCTTCCCAAGTTTCACTACTTTATTTTCATATGTATCTCTGA 780
Db 51354 TCTGGGTAAATACCTTTTCTTCCCAAGTTTCACTACTTTATTTTCATATGTATCTCTGA 51295

Qy 781 GATAGAGAAATATTTCACTCAGTGCTGCTAAAATGTTTCTTATAACTCGTTTATCCTTT 840
Db 51294 GATAGAGAAATATTTCACTCAGTGCTGCTAAAATGTTTCTTATAACTCGTTTATCCTTT 51235

Qy 841 TAGGTCCTTCCAGAACTCTCTATTGGTACTGAACTCAAATGGGTACTTTCTTCAACATT 900
Db 51234 TAGGTCCTTCCAGAACTCTCTATTGGTACTGAACTCAAATGGGTACTTTCTTCAACATT 51175

Qy 901 TATTTCTTTAGAATAAGTAATAAGAATTTTATAAGCTTTTATATTTTACGTAATTGA 960
Db 51174 TATTTCTTTAGAATAAGTAATAAGAATTTTATAAGCTTTTATATTTTACGTAATTGA 51115

Qy 961 GACTATTGAAATCCAGTTAAGTCTCTCTACTGTGTTGAGAGGCATTGATTCAAGTACCT 1020
Db 51114 GACTATTGAAATCCAGTTAAGTCTCTCTACTGTGTTGAGAGGCATTGATTCAAGTACCT 51055

Qy 1021 GTGTACTTTCTGTGCTGCCAAAACAGATCACCTCAAATAAGCGGCTTAAATAATAG 1080
Db 51054 GTGTACTTTCTGTGCTGCCAAAACAGATCACCTCAAATAAGCGGCTTAAATAATAG 50995

Qy 1081 AACTTAAGTTCTCGTGAT 1098
Db 50994 AACTTAAGTTCTCGTGAT 50977

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6. Claims 50-52, 56-59 and 61-66 are rejected under 35 U.S.C. 102(a) and (b) as being anticipated by Osoegawa et al (Genomics (1998)52:1-8) as evidenced by Genbank Accession No. AC022578 and an email from Pieter de Jong (attached).

Osoegawa teaches synthesis of BAC chromosome libraries (abstract). In particular, Osoegawa teaches the synthesis of a particular BAC library termed RPCI-11 (also called RP11) which was grown in bacterial host cells using recombinant vectors which were placed onto filters and the nucleic acid was isolated (page 2 and page 3, column 1).

A specific isolated BAC, RP11-15C20, which is in a composition of this library and which is at a specific location on the arrays sold by the BACPAC consortium, comprises 543 contiguous nucleotides from nucleotides 3899-4996 of SEQ ID NO: 179 (see nucleotides 555-1098 of the query sequence). As shown by the alignment below, this BAC has close match with the reference sequence.

```

Query Match          90.7%; Score 996; DB 2; Length 183485;
Best Local Similarity 99.8%; Pred. No. 0;
Matches 1096; Conservative 0; Mismatches 2; Indels 0; Gaps 0;

      1 GTTCTCTGTTCCCTGCATTTTATTTTATTTGATGGAGGGGACAAATAATTATTTCTGT 60
      |||
76159 GTTCTCTGTTCCCTGCATTTTATTTTATTTGATGGAGGGGACAAATAATTATTTCTGT 76218

      61 TTAGTAACAGAGCAGGGTATTTTGAATTTATTAGGGTCTTTTCTGCAGTCTGGGTTTCC 120
      |||
76219 TTAGTAACAGAGCAGGGTATTTTGAATTTATTAGGGTCTTTTCTGCAATCTGGGTTTCC 76278

      121 TGTGTACACAAAGCTACCTTTCAATATTTTATTGTTTCTGTTAAGATTAAATCAATAG 180
      |||
76279 TGTGTACACAAAGCTACCTTTCAATATTTTATTGTTTCTGTTAAGATTAAATCAATAG 76338

      181 AGGAATAAATAGCTATCTTCAAACATAAGACCCAAAGGAAAAAGATTATAGTGATGTTTC 240
      |||
76339 AGGAATAAATAGCTATCTTCAAACATAAGACCCAAAGGAAAAAGATTATAGTGATGTTTC 76398

      241 TGTACCTTATTTTACCTGTGACTTTGTACCATTAACCTTGTCACTGAGATGTTTGA 300
      |||
76399 TGTACCTTATTTTACCTGTGACTTTGTACCATTAACCTTGTCACTGAGATGTTTGA 76458

      301 TTAAATTTTATAGCTTGCTTTTCTGTTTGTAGGACACTCTTTTCTTGAATTGTT 360
      |||
76459 TTAAATTTTATAGCTTGCTTTTCTGTTTGTAGGACACTCTTTTCTTGAATTGTT 76518

      361 TTTATCAGCTTTTCGTTTGCAAGGCTAGTGATGATTCTCTGTTCTGTATAAAGTATTGTT 420
      |||
76519 TTTATCAGCTTTTCGTTTGCAAGGCTAGTGATGATTCTCTGTTCTGTATAAAGTATTGTT 76578

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      421 GACTCATTCTGAAGGGAGTTT TAGTAATTTAAGAGGTTATAAGTTTTTAAATAAAAGGT 480
      |||
76579 GACTCATTCTGAAGGGAGTTT TAGTAATTTAAGAGGTTATAAGTTTTTAAATAAAAGGT 76638
      |||
      481 TTATTAATTTATATATATTAAGAGGCATTTTAAATAAAATTTTTTTTAAATGACATTT 540
      |||
76639 TTATTAATTTATATATATTAAGAGGCATTTTAAATAAAATTTTTTTTAAATGACATTT 76698
      |||
      541 TTACACCTTTCAACTCTAGGTTTAAAAAATAAGTGGTTCACAGTAGTTCCTGCAGAAGAA 600
      |||
76699 TTACACCTTTCAACTCTAGGTTTAAAAAATAAGTGGTTCACAGTAGTTCCTGCAGAAGAA 76758
      |||
      601 TATTTTCTTTTACATAGAATTTTAAAGCTGAAGAGAAGTAGTAGTAGGTCCATGAGATTT 660
      |||
76759 TATTTTCTTTTACATAGAATTTTAAAGCTGAAGAGAAGTAGTAGTAGGTCCATGAGATTT 76818
      |||
      661 ATGATCTGTGCTTGGCAGGTAACCTGCTTCCAACAAATTTAGTTGGATTTTTCTTGGAT 720
      |||
76819 ATGATCTGTGCTTGGCAGGTAACCTGCTTCCAACAAATTTAGTTGGATTTTTCTTGGAT 76878
      |||
      721 TCTGGGTAAATACCTTTTTCTTCCCAGTTTCACTACTTTATTTTCATATGTATCTCTGA 780
      |||
76879 TCTGGGTAAATACCTTTTTCTTCCCAGTTTCACTACTTTATTTTCATATGTATCTCTGA 76938
      |||
      781 GATAGAGAAATATTTCACTCAGTGCTGCTAAAATTGTTCCCTTATAACTCGTTTATCCTTT 840
      |||
76939 GATAGAGAAATATTTCACTCAGTGCTGCTAAAATTGTTCCCTTATAACTCGTTTATCCTTT 76998
      |||
      841 TAGGTCCTTCCAGAATCTCTCATTTGGTACTGAAACTCAAATGGGTACTTTCTTCAACATT 900
      |||
76999 TAGGTCCTTCCAGAATCTCTCATTTGGTACTGAAACTCAAATGGGTACTTTCTTCAACATT 77058
      |||
      901 TATTTCTTTAGAATAAGTAATAAGAATTTTATAAGCTTTTTTATATTTACGTAATTTGA 960
      |||
Db 77059 TATTTCTTTAGAATAAGTAATAAGAATTTTATAAGCTTTTTTATATTTACGTAATTTGA 77118
      |||
Qy 961 GACTATTGAAAATCCAGTTAAGTCTCTCTACTGTGTTGAGAGGCATTGATTCAAGTACCT 1020
      |||
Db 77119 GACTATTGAAAATCCAGTTAAGTCTCTCTACTGTGTTGAGAGGCATTGATTCAAGTACCT 77178
      |||
Qy 1021 GTGTTACTTTCTGTGCTGCCAAAACAGATCACCTCAAACCTAAGCGGCTTAAATAATAG 1080
      |||
Db 77179 GTGTTACTTTCTGTGCTGCCAAAACAGATCACCTCAAACCTAAGCGGCTTAAATAATAG 77238
      |||
Qy 1081 AACTTAAGTTCTCGTGAT 1098
      |||
Db 77239 AACTTAAGTTCTCGTGAT 77256

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The email of Pieter de Jong indicates that filters from the RPCI-11 library were first publicly available, used and sold on August 1, 1997. As shown by the alignment above, the filter with RP11-15C20 inherently comprises 543 contiguous nucleotides from nucleotides 3899-4996 of SEQ ID NO: 179.

With regard to claim 51, Osoegawa teaches that the sequences were in Bac vectors (see page 1, column 2, subheading "BAC/PAC vector preparation").

With regard to claim 52, Osoegawa teaches that the vectors were in bacterial host cells (see page 2, column 1).

With regard to claim 56, Osoegawa teaches that the sequences were in vectors, and the vector sequence can function as a label for the detection of the target sequence (see page 1, column 2. To explain, a DNA sequence may itself be a label, and frequently is used as such, since specific DNA can be detected by hybridization).

With regard to claims 57-58, Osoegawa teaches that the oligonucleotide is attached, indirectly, to a solid support (see page 2, column 1 and email, where filters were sold).

With regard to claims 59 and 61-66, Osoegawa teaches a library which would comprise the RPCI-11 library, which Genbank Accession No. AC022578 shows has 543 contiguous nucleotides in the claimed region (see alignment above).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osoegawa et al (Genomics (1998)52:1-8) in view of Capecchi et al (Science (1989) 244:1288-1292).

Osoegawa teaches vectors that comprise sequences of interest as discussed above.

Capecchi teaches the use of homologous recombination to form host cells and mammals (see page 1280, figure 1, for example).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to screen each of the sequences of Osoegawa for functional activity using the homologous recombination method of Capecchi since Capecchi states "Targeted disruption of these genes may not only reveal the phenotypes associated with inactivation of the individual genes, but through epistasis and molecular analyses, may also help define the developmental network controlling early mouse morphogenesis (see page 1292, column 1)." Thus, an ordinary practitioner, interested in identifying what phenotype is associated with the sequence of the sequences of Osoegawa would have been motivated by Capecchi to use targeted disruption in order to define the phenotype of the genes with which the sequence of Osoegawa are associated.

Allowable Subject Matter

10. Claim 60 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: Claim 60 is drawn to the complete SEQ ID NO: 179. No such sequence was found in the sequence search and while the evidence from the chromosome 8 hits is that there is generally 99.8% or so alignment with hundreds of contiguous basepairs, there is no evidence that Weier is inherently identical over the entire length of SEQ ID NO: 179. Therefore, the claim to the entire sequence is novel and unobvious.

Response to Arguments

12. Applicant's arguments filed December 22, 2004 have been fully considered but they are not persuasive.

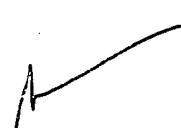
Applicant argues that the Gu reference should fall because there is no evidence that chromosome 8 inherently comprises the sequence of the claimed invention. The rejection has been amended to cite an evidentiary reference which shows a chromosome 8 sequence that is highly identical to claimed sequence. This provides the evidence necessary to establish that chromosome 8 more likely than not inherently teaches a sequence meeting the requirements of the claims under rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey Fredman
Primary Examiner
Art Unit 1637
